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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/363,100 07/29/99 MICKLE

D 50074/004003

EXAMINER

HM12/0117

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AFREMOVA, V

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

01/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/363,100

Applicant(s)

Mickle et al.

Examiner

Vera Afremova

Group Art Unit

1651

☒ Responsive to communication(s) filed on Dec 11, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) 14-24 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Claims 14-24 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7 filed 12/11/2000.

**Claims 1-13 are under examination in the instant office action.**

#### ***Claim Rejections - 35 U.S.C. § 112***

Claims 2-9, 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 , 4-9 and 13 are indefinite and incomplete because it is unclear as claimed when in the method of administration of the claim 1 the mesenchymal cells (MSC) were “cultured” or “co-cultured” or “exposed” to treatment or “not passaged” . The method seem to encompass incorporation of additional active step(s) which is (are) omitted in the claims, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Claims 3 and 12 are indefinite and incomplete because they appear to omit some active steps. It is unclear as claimed what parameters are evaluated or what active steps are required to evaluate the effects as claimed.

#### ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,736,396

[A].

The claims are directed to a method for treating damaged myocardial tissue wherein the method comprises a step of administering to the myocardial tissues a cellular suspension containing mesenchymal stem cells MSC. Some claims are further drawn to the use of mesenchymal cells isolated from bone marrow and to inducing differentiation of mesenchymal cells by exposing cells to 5-azacytidine at concentration of 1-100  $\mu$ M or 10  $\mu$ M. Some claims are further drawn to culturing the mesenchymal cells for 7 days. Some claims are further drawn to the use of MSC which were not passaged.

US 5,736,396 [A] teaches a method for treating in individual in need of mesenchymal cells of a particular lineage including myogenic lineage wherein the method comprises a step of administering to the individual in need thereof a composition with mesenchymal stem cells which have been induced to differentiate ex vivo by contacting with a bioactive factor to induce differentiation of the particular lineage including myogenic lineage (col. 30; col. 1, lines 57-67; col. 2, lines 1-10). The bioactive factor is a 5-azacytidine or analog thereof which induces myogenic differentiation of MSC on vitro (example 5). The cited patent teaches the use of MSC isolated from bone marrow and exposing MSC to 5-aza at concentration of 1-50  $\mu$ M or 10  $\mu$ M (col. 17, line 7). The cited method teaches culturing MSC for 7 days (col. 17, line 10) or co-culturing MSC

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with cells of myocardial lineage during differentiation. The patent teaches successful formation of myotubes after MSC exposure to different concentration of 5-aza (see for example tables 2 or 3). The cited method encompasses administration of autologous MSC (col. 2, line 8) and administration of MSC by injection (col.5, line 16). The cited method teaches the use of MSC from the first passage for induction of differentiation with 5-aza (col.16, line 22). According to applicants' definitions (page 6, par. 2) the use of the second passage of cells is excluded or the use of bone marrow derived cells isolated from the second vessel are no permitted. Thus, the cited method seems to anticipate active step and all structural elements required by the claimed invention.

No claims are allowed.

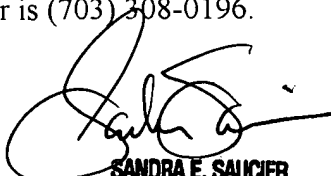
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova,

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January 12, 2001.



**SANDRA E. SAUCIER**  
**PRIMARY EXAMINER**